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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
DEVI, SARVAMANGALA J N	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 09/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/022,832	COUTURE ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31 and 34-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-31 and 34-46* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Restriction

1) Claims 32 and 33 have been canceled.

Claims 21, 30 and 31 have been amended. New claims 34-46 have been added.

Claims 1-31 and 34-36 are pending and are under examination.

2) Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-16, drawn to polynucleotides, or fragments or analogs thereof; vectors, host cells; and a method of using the host cells, classified in class 536, subclass 23.7.

II. Claims 17, 18, 21, 34, 45 and 46, drawn to polypeptides, fragments or analogs thereof, and compositions and kits comprising the same, classified in class 530, subclass 350.

III. Claims 19 and 20, drawn to a chimeric polypeptide comprising two or more polypeptides, fragments or analogs thereof, classified in class 424, subclass 192.1

IV. Claims 22-29, and 35-42, drawn to a method of treating chlamydial infection comprising administering a composition comprising a polypeptide, fragments or analogs thereof, classified in class 424, subclass 263.1.

V. Claims 30 and 43, drawn to a method for diagnosis of a chlamydial infection using an antibody to a polypeptide, or a fragment or analog thereof, classified in class 435, subclass 7.1.

VI. Claims 31 and 44, drawn to a method for diagnosis of a chlamydial infection using a polypeptide, or a fragment or analog thereof, classified in class 435, subclass 7.36.

3) Upon election of one of inventions I through VI, Applicant should further elect one of the polynucleotides, polypeptides or chimeric polypeptides recited in the claim(s) of inventions I, II and III respectively, the method of treating using one of the polypeptides as recited in the claims of invention IV, the method of diagnosing using an antibody to one of the polypeptides as recited in the claim(s) of invention V, or the method of diagnosing using one of the polypeptides as recited in the claim(s) of invention VI. This is a restriction requirement as opposed to a species election, because each of the claimed product, or the product used in the claimed methods, has a structure or amino acid or nucleotide composition that is significantly distinct from the other. A structural search for one product is not coextensive with the other due to the structural diversity.

4) The inventions are distinct, each from the other because of the following reasons.

Inventions I-III are patentably distinct products.

The polynucleotide of invention I and polypeptide of invention II are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the instant claims, a polynucleotide of invention I does not necessarily encode a polypeptide of invention II. For example, as disclosed in the specification, SEQ ID NO: 2 is 258 amino acids in length, whereas the nucleic acid fragments of claim 1(e) require only 18-30 nucleotides (which would encode a polypeptide fragment of 6-10 amino acids in length). Similarly, the nucleic acid molecule of claim 1(f) is complementary to the coding sequence, and therefore would not encode the polypeptide of invention II. Furthermore, the information provided by the polynucleotide of invention I can be used to make a materially different polypeptide than that of invention II. For example, a nucleic acid which hybridizes to a polynucleotide that encodes SEQ ID NO: 2, even under stringent conditions, encompasses molecules which contain point mutations, splice sites, frameshift mutations, or stop codons which would result in use of a different open reading frame, and thus encode a protein that lacks any significant structure in common with SEQ ID NO. 2. In addition, while a polypeptide of invention II can made by methods using some, but not all, of the polynucleotides that fall within the scope of invention I, it can also be recovered from a natural source using biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. It can also be obtained by chemical synthesis without the use of vector-containing host cells. For these reasons, inventions I and II are patentably distinct.

Furthermore, searching the inventions I and II together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions I and II have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent

literature. Prior to the concomitant isolation and expression of the sequence of interest, there may be journal articles devoted solely to polypeptides which would not have described the polynucleotides. Similarly, there may have been 'classical' genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. In addition, the polypeptide claims include polypeptides having 70% or 95% identity to the sequence identified. This search requires an extensive analysis of the art retrieved in a sequence search and would require an in-depth analysis of technical literature. The scope of polynucleotides as claimed extend beyond the polynucleotides that encode the claimed polypeptides as explained above; furthermore, a search of the nucleic acid molecules of claim 1(e) would require an oligonucleotide search, which is not likely to result in relevant art with respect to the polypeptide of invention II. As such, it would be burdensome to search the inventions I and II together.

Inventions III and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentably, and (2) that the subcombination has utility by itself or in other combinations (MPEP 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed for patentability because the chimeric combination is an individually distinct polypeptide having a distinct amino acid sequence. The subcombination polypeptides comprise individually distinct sequences and have their own separate utility as diagnostic antigens, therapeutic or prophylactic agents, or substrates for catalytic enzymes. The patentability of the combination does not necessarily rely solely upon the patentability of subcombination alone for its patentability as evidenced by the presentation of separate claims to subcombination.

Inventions IV, V, and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method of treating chlamydial infection using a polypeptide (invention IV), the method for diagnosis of a chlamydial infection using an antibody to a polypeptide (invention V), and the method for diagnosis of a chlamydial infection using a polypeptide (invention VI) are all unrelated as they comprise distinct steps and utilize

different products demonstrating that each method has a different mode of operation. Each invention performs the method using a structurally and functionally divergent material. Moreover, the methodology and materials necessary for treating a chlamydial infection differ significantly for each of the materials. For diagnosis using the polypeptide, quantitation of labeled polypeptide may be used. For diagnosis using the antibody, quantitation of labeled antibody may be used. For treatment of a chlamydial infection using the polypeptide, the polypeptide is administered to a host having chlamydial infection using any mode of administration. Therefore, each method is divergent in materials and steps. For these reasons, the inventions IV, V and VI are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions IV, V and VI have a separate status in the art as shown by their diverse classifications and/or subclassifications. As such, it would be burdensome to search the inventions IV, V and VI together.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides of invention II can be used as diagnostic reagents or as substrates in enzymatic reactions as opposed to their use in treating a chlamydial infection.

Inventions II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides of invention II can be used as prophylactic agents or as substrates in enzymatic reactions as opposed to their use in diagnosing a chlamydial infection.

Inventions I and either IV, V or VI are unrelated because the polynucleotide product of invention I is not used or otherwise involved in the process of invention IV, V or VI.

Inventions V and either inventions I, II or III are unrelated because the product of invention I, II or III is not used or otherwise involved in the process of invention V.

Searching the invention II and inventions IV and VI together would impose serious search burden. The invention II and inventions IV and VI have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polypeptides and the method of treating chlamydial infection using a polypeptide or the method of diagnosing a chlamydial infection are not coextensive. For example, invention II encompasses molecules which are claimed in terms of 70% or 95% identity to SEQ ID N0. 2, which are not required for the search of invention IV or VI. In contrast, the search for invention IV or VI would require a text search for the method of treating or diagnosing a chlamydial infection in addition to a search for SEQ ID N0. 2. Prior art teaching a polypeptide which is 70% or 95% identical to SEQ ID N0. 2 would not necessarily be applicable to the method of using the polypeptide comprising SEQ ID N0. 2. Moreover, even if the polypeptide product were known, the method of treatment or diagnosis which uses the product may be novel and unobvious in view of the preamble or active steps.

Invention III and inventions IV, V or VI are unrelated because the product of invention III is not used or otherwise involved in the process of invention IV, V or VI.

Searching the product of invention V requires the search for the antibody since the method of diagnosing a chlamydial infection uses an antibody. A search for an antibody is not coextensive with a search for a polynucleotide or polypeptide

The inventions of Groups I, II, III, IV, V and VI have a separate status in the art as shown by their different classifications and/or subclassifications. As such, it would be burdensome to search any combination of the inventions of Groups I, II, III, IV, V or VI together.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and/or subclassification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

5) The Office has required restriction between product and process claims. Where Applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process

claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. § 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See 'Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b),' 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of amendments, responses or papers is (703) 872-9306.

7) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

8) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

September, 2004

S. DEVI, PH.D.
PRIMARY EXAMINER